

Air Protection Branch

4244 International Parkway
Suite 120
Atlanta, Georgia 30354
404-363-7000

November 8, 2019

Michelle Quinn
Becton, Dickinson and Company
SVP, Chief Ethics and Compliance Officer
1 Becton Drive
Franklin Lakes, New Jersey 07417

Dear Ms. Quinn:

On November 5, 2019, the Georgia Environmental Protection Division (EPD) received the first weekly report required by Attachment A, Condition 16, of the Consent Order entered on October 28, 2019, by the Newton County Superior Court. Condition 16 requires, in pertinent part, that Becton, Dickinson and Company (BD):

shall submit weekly reports of the daily number of lots sterilized, ethylene oxide usage, ethylene oxide destructed through the RTO, and sterilization cycle reports to demonstrate 24 hours of aeration time at the Covington and Madison facilities to EPD.

The weekly report for the period October 28, 2019 through November 3, 2019, documents that 142.5 lots were sterilized in 62 loads. Some of the loads began the sterilization and aeration process prior to programming changes to implement Condition 16 on October 29, 2019. The weekly report for the period ending November 3, 2019, documents that aeration times for six sterilization lots at BD Madison were less than the required 24 hours after implementation of Condition 16, in violation of the Consent Order. The two sterilization loads containing the six lots are summarized below:

Location	Sterilization Load #	Vessel	Lots	Start Date	Time in Aeration, minutes (hours)
Madison	200400	5	3	11/1/2019	852 (14.2 hours)
Madison	200399	5	3	11/3/2019	855 (14.25 hours)

BD reported this information to EPD and the Office of the Attorney General immediately upon discovering the violations. Specifically, the weekly report was timely submitted by email late in the evening on November 4, 2019, and BD requested a call contemporaneously with the submission of the weekly report. BD then notified EPD and the Office of the Attorney General of the violations during a November 5, 2019, morning conference call. BD explained that sterilization loads #200400 and #200399 were FDA validation loads required for an ethylene oxide usage reduction project. BD attributes the violations of Condition 16 to staff not understanding that the 24 hour aeration time applied to all sterilization loads, including FDA validation loads containing no saleable product. During the call on November 5, 2019, you informed EPD that BD has advised staff at BD Madison that the 24 hour aeration time applies to all sterilization loads.

As a result of the violations, EPD conducted an unannounced site visit at BD Madison this morning. During the site visit EPD staff observed the aeration chambers, reviewed BD Madison records related to the holding period in the aeration chambers, and interviewed BD Madison staff regarding their understanding of how long sterilization loads must be held in the aeration chambers. EPD's site visit today confirmed that staff at BD Madison now understands that all sterilization loads must be held in the aeration chambers for 24 hours.

Under the Consent Order, EPD and BD agreed that BD would hold sterilized devices in the aeration chambers for 24 hours at both the Madison and Covington plants, with the objective of reducing the fugitive emissions of ethylene oxide to the atmosphere that may occur following sterilization. In assessing the violations in question, EPD has considered that keeping the sterilized devices in an aeration chamber for 24 hours allows capture and destruction of more fugitive emissions of ethylene oxide by the regenerative thermal oxidizer (RTO) than would be captured and destroyed in 14 hours of aeration. EPD is also aware that emissions of ethylene oxide during aeration occur more rapidly immediately following sterilization and diminish over time. In other words, fugitive emissions of ethylene oxide are significantly greater during hours 1-14 than during hours 15-24.

Today's site assessment determined that BD Madison was otherwise adhering to the applicable conditions of the Consent Order. Based upon the entirety of the circumstances of the present violations, EPD has decided not to take action against BD for the violations at this time. To be clear, however, EPD expects BD to comply with all conditions of the Consent Order at all times. Accordingly, BD should expect any failure to comply with the Consent Order in the future to result in the EPD Director pursuing contempt in Newton County Superior Court, barring extraordinary circumstances.

Please contact me at 404-363-7016 or karen.hays@dnr.ga.gov if you have any questions regarding this letter or the conditions of the Consent Order.

Sincerely,

Karen Hays, P. E.
Chief
Air Protection Branch

cc: Peggy Eckrote, Senior Assistant Attorney General, Office of the Attorney General
Robin Leigh, Senior Assistant Attorney General, Office of the Attorney General
Sean Taylor, Manager, Stationary Source Compliance Program